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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,937	10/25/2001	Christopher R. Ralph	1759.17239-FOR	8882

7590

09/09/2004

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EXAMINER
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RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/001,937

Applicant(s)

RALPH ET AL

Examiner

Anu Ramana

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 5-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/28/04; 6/1/04; 3/15/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Haig (US 4,494,535).

Haig discloses a tool 10 for establishing a percutaneous path into bone having a cannula 12 with an elongated opening 20 in its sidewall and a surface 17 on the distal end of the cannula to aid in placement of the cannula in bone (Fig. 1, col. 1, lines 41-68 and col. 2, lines 1-3).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. (US 5,380,290) in view of Scholten et al. (US 4,969,888).

Makower et al. disclose a body access device or cannula 14 having a slotted opening 26 along a sidewall for placement of an elongated element such as a catheter in a body (Figs. 1, 9 and 10, col. 1, lines 6-12 and col. 6, lines 23-68).

Makower et al. disclose all elements of the claimed invention except for an expandable structure.

Scholten et al. teach insertion of an expandable structure such as balloon 65 through a cannula 30 for the purpose of compacting osteoporotic bone marrow during fracture fixation (Fig. 24, col. 1, lines 6-10 and lines 67-68, col. 2, lines 1-20).

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Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized an expandable structure with the Makower et al. device, as taught by Scholten et al., for the purpose of fracture fixation.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Witt (US 4,842,585) in view of Scholten et al. (US 4,969,888).

Witt discloses a cannula having an elongated hollow tube 12 with a closed front or "solid bore" and an opening 12 for safe positioning of a catheter (col. 1, lines 51-53, col. 2, lines 44-68 and col. 3, lines 1-33).

Witt discloses all elements of the claimed invention except for an expandable structure.

Scholten et al. teach insertion of an expandable structure such as balloon 65 through a cannula 30 for the purpose of compacting osteoporotic bone marrow during fracture fixation (Fig. 24, col. 1, lines 6-10 and lines 67-68, col. 2, lines 1-20).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized an expandable structure with the Witt device, as taught by Scholten et al., for the purpose of fracture fixation.

Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. (US 5,380,290) in view of Scholten et al. (US 4,969,888), as applied to claim 6, further in view of Lombardo (US 6,488,653).

Makower et al. discloses all elements of the claimed invention except for an expandable structure having radiopaque markers.

Scholten et al. teach insertion of an expandable structure such as balloon 65 through a cannula 30 for the purpose of compacting osteoporotic bone marrow during vertebral body fracture fixation wherein insertion of the balloon is monitored fluoroscopically (Fig. 24, col. 1, lines 6-10 and lines 67-68, col. 2, lines 1-20).

Lombardo teaches a dilatation balloon having longitudinally positioned radiopaque markers for fluoroscopic visualization of the balloon (Figs. 5 and 6, col. 2, lines 41-50 and col. 5, lines 31-63).

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It would have been obvious to one of ordinary skill in the art to substitute a balloon with radiopaque markers as, for example, taught by the Lombardo reference for the balloon of the device of the combination of Makower et al. and Scholten et al. wherein so doing would amount to mere substitution of one functionally equivalent structure for another within the same art and the selection of any of these structures would work equally well in the claimed device.

The method steps of claims 10-14 are performed during normal use of the Makower et al.-Scholten et al.-Lombardo device during fracture fixation.

### *Allowable Subject Matter*

The indicated allowability of claims 5, 6 and 9 in the office action mailed on November 25, 2003 is being withdrawn in view of the new grounds of rejection made in this office action. Accordingly, the finality of the office action is also being withdrawn.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

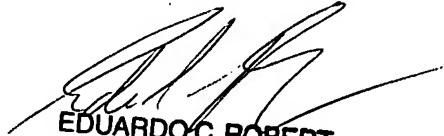
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anunadha Ramana*  
September 7, 2004

  
EDUARDO C. ROBERT  
PRIMARY EXAMINER